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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/599,152	06/21/2000	David J. Yang	UTXC:664	6919

7590  
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05/20/2005

EXAMINER

JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 05/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/599,152

Applicant(s)

YANG ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 2/25/05; 12/30/04; & 6/1/04.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 2-4, 6-35, 37-41, 52, 53 and 55-61 is/are pending in the application.
- 4a) Of the above claim(s) 56-61 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7, 11-14, 16-22, 24-29, 52, 53 and 55 is/are allowed.
- 6) ☒ Claim(s) 2-4, 6, 8-10, 15, 23, 30-35 and 37-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/30/04; 2/25/05; & 6/1/05
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **ACKNOWLEDGEMENTS**

1. The Examiner acknowledges receipt of the acceptable RCE filed 2/25/05. In addition, the Examiner acknowledges the amendment filed 12/20/04 wherein the specification was amended; and the claim status is as follows: claims 1, 5, 36, 42-51, and 54 are canceled and claims 7, 11, 16, 24, 33, 35, 52, 53, and 55 are amended.

**Note:** Claims 2-4,6-35,37-41,52,53 and 55-61 are pending.

## **RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS**

2. The Applicant's arguments filed 12/30/04 to the rejection of claims 2-4, 6, 8-10, 15, 23, 30-35, and 37-41 made by the Examiner under 35 USC 112 have been fully considered and deemed non-persuasive for reasons of record in the office action mailed 6/25/04 and those set forth below.

### **112 First Paragraph Rejections**

The rejection of claims 2-4, 6, 8-10, 15, 23, 30, 31, 33-35, and 37-41 under 35 USC 112, first paragraph, because the specification while being enabling for methods of synthesizing a radiolabeled ethylenedicysteine (EC) complex wherein the tissue specific ligand is selected from (a) anticancer agents methotrexate, doxorubicin, tamoxifen, paclitaxel, topotecan, LHRH, mitomycin C, etoposide, tomudex, podophyllotoxin, mitoxantrone, camptothecin, colchicines, endostatin, fludarabin, and gemcitabine; (b) tumor markers PSA, ER, PR, CA-125, CA-199, CEA, AFP, interferon, BRCA1, HER-2/neu, cytoxan, p53, and endostatin; (c) folate receptor targeting agents folate, methotrexate, folic acid, and tomudex; (d) tumor apoptotic cell targeting ligands and

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tumor hypoxia targeting agents annexin V, nitroimidazole, mitomycin, colchicine, and metronidazole; (e) glutamate pentapeptide; (f) glucose mimics neomycin, kanamycin, entamycin, paromycin, amikacin, tobramycin, netilmicin, ribostamycin, sisomicin, micromicin, lividomycin, dibekacin, isepamicin, astromicin, glucosamine, and aminoglycoside; and (g) glucose, does not reasonably provide enablement for all tissue specific agents wherein the agents are anticancer agents, tumor markers, folate receptor targeting ligands, tumor apoptotic cell targeting ligands, tumor hypoxia targeting ligands, or agents that mimic glucose, is MAINTAINED for reasons of record in the office action mailed 6/25/04.

Applicant's arguments may be summarized as follows: (1) each of the terms 'anticancer agent', 'tumor marker', 'folate receptor targeting ligand', 'tumor apoptotic cell targeting ligand', 'tumor hypoxia targeting ligand', and 'an agent that mimics glucose' are readily discernible in light of the specification; and (2) the declaration by Jerry Bryant discloses that one would have an understand of the element encompassed by the terms.

All of Applicant's arguments and the declaration set forth in the response filed 12/30/04 have been considered but not found persuasive. In essence, the rejection is being maintain on the same basis as set forth in the previous office actions. For example, undue experimentation is necessary to determine what specific species are encompassed by the instant invention since the invention is directed to all species, known and unknown, which are encompassed by the terms above. Also, the terms are such that a person of ordinary skill in the art would be forced to engage in undue

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experimentation, with no assurance of success, because some species are encompassed by multiple categories. Hence, clarity of Applicant's claims is needed and undue experimentation is necessary to practice the invention. Also, while art related to EC may be known, art relating to all the tissue specific ligands is not since novelty of the invention is directed to the radiolabeling of the specific tissue ligands with EC, not EC itself. Thus, what the tissue specific ligands that are enabled by the instant invention are of concern. As a result, species which were not envisioned by Applicant are not properly enabled. In other words, the invention encompasses species in which Applicant had no knowledge what the species are and that they could be radiolabeled with EC. Furthermore, the claims as written may be considered as 'reach thru' claims since they aim to claim later discovered subject matter.

**112 Second Paragraph Rejections**

I. The rejection of claims 2-4, 6, 8-10, 15, 23, 30, 31, 33-35, and 37-41 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention is MAINTAINED for reasons of record in the office action mailed 9/29/03 and those below.

Applicant asserts that the 112, second paragraph, rejections should be withdrawn based on the arguments presented above for the 112, first paragraph, rejection and based on the declaration submitted by Jerry Bryant.

Applicant's arguments are not found persuasive and are maintained for the reasons set forth in response to the 112, first paragraph, rejections above and those of record in the office action mailed 6/25/04. In particular, one cannot ascertain what is

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being claimed by the terms 'anticancer agents', 'tumor markers', 'folate receptor targeting ligands', 'tumor apoptotic cell targeting ligands', 'tumor hypoxia targeting ligands', or 'agents that mimic glucose' (also see response below regarding terms falling within multiple groups).

II. The rejection of claim 32 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention is MAINTAINED for reasons of record in the office action mailed 6/25/04 and those set forth below.

Applicant asserts that the term 'octreotide' is clear and unambiguous.

The term 'octreotide' is ambiguous because in the response filed 4/8/04, Applicant asserted that term 'octreotide' was not removed from claim 32 because it may be an anti-cancer agent as set forth in Table 2, page 36, of the specification. However, while Applicant does disclose 'octreotide' on page 36, Table 2, as an anti-cancer agent, page 5, lines 8 and 11 disclose that one of the preferred tissue specific ligand is a peptide. Also, it is noted that page 6, lines 14-15, list 'octreotide' as a peptide. Hence, Applicant is claiming that 'octreotide' as being encompassed both as a peptide and as an anti-cancer agent. As a result, when prior art was presented rendering *peptides* obvious, Applicant's argument for not deleting the term from the claims was that 'octreotide' is an anti-cancer agent and since the term 'peptide' had been deleted, art should be applied as it relates to 'octreotide' being an anti-cancer agent. Hence, there is definitely ambiguity in what is being claimed. When prior art is applied, one cannot change the definition of a term. Thus, the Examiner is requesting that the record be

clarified as to which what Applicant actually intends by the term. Furthermore, it should be noted that Applicant's response supports the Examiner's position that based on the terms listed in the 112, first and second paragraph, rejections, one cannot readily determine what is encompassed by the terms of the instant invention since terms specific targeting ligands may be classified in one or more categories. As a result, how is one to determine exactly what the terms are encompass by the instant invention if when prior art is cited against terms that are encompassed by multiple categories, Applicant's position becomes that the term should remain because it falls within another category? Hence, the rejection is being maintained on the basis that 'octreotide' is a peptide that is listed as a peptide in the specification and art has previously been cited against peptides.

### **COMMENTS/NOTES**

3. Applicant is reminded that each application is examined on a case by case basis. In addition, the principles and tools that Examiner's need to effectively examine applications are constantly being modified. As a result, just because a certain action was not taken in another action (i.e., 09/434,313) should not be interpreted as the action not being proper and appropriate in the instant invention.

### **WITHDRAWN CLAIMS**

Claims 56-61 are withdrawn from consideration as being directed to a non-elected invention (see 37 CFR 1.142(b) and MPEP 821.03) for reasons of record in the office action mailed 6/25/04.

**Note:** Applicant's response was reviewed and not found persuasive for reasons of record. In particular, the claims read on any and all ligands which encompasses more than the groups set forth in the instant invention.

#### **ALLOWABLE CLAIMS**

4. Claims 7, 11-14, 16-22, 24-29, 52, 53, and 55 are allowable over the prior art of record.

**Note:** The claims are distinguished over the prior art of record for reasons of record in the office action mailed 9/29/03.

#### **ADDITIONAL COMMENTS/NOTES**

5. The declaration filed by Jerry Bryant along with the response submitted 12/30/04 is acknowledged. The declaration has been considered.


6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones  
Primary Examiner  
Art Unit 1616

May 13, 2005